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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,090	10/23/2003	Shigeru Nemoto	KITO2.001DV5	8325

20995 7590 07/01/2008  
KNOBBE MARTENS OLSON & BEAR LLP  
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EXAMINER
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DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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07/01/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/692,090	<b>Applicant(s)</b> NEMOTO, SHIGERU	
	<b>Examiner</b> MATTHEW F. DESANTO	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,9,10,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,9,10,12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05-15-2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3, 9, 10, 12, 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for having a degree of roughness, the claim and specification does not reasonably provide enablement for a flange having a roughness of about No. 20-1500. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The examiner has not been able to find a standard of roughness, which causes a problem with the claims and specification since there is no way to figure out the scope of the claim and how to determine the roughness of an element that is between No. 20 to 1500 as expressed in terms of counts of sand paper. The problem that occurs is that counts of sand paper is determined by the average diameter size of the "sand" or grit in the paper, but the problem is that the claim in the instant invention never recites any element that has the specific diameter size in accordance with the counts of sandpaper. Thus the examiner doesn't want to limit the applicant to an average particle size since there are other ways to create roughness, but the specific doesn't give any way to determine the roughness that is created by these other ways. Therefore, one of ordinary skill has no way to determine roughness that is created by these other ways, unless they use the average

diameter size of the particles, which leaves the examiner with an indefinite claim. If the applicant wishes to omit particles from the flange (as presently presented), then there is no way to determine roughness in terms of counts of sandpaper due to the lack of teaching from the specification. The examiner has read through the NPL cited in the IDS dated 5-15-08, but this fails to provide any way of determining roughness from a non-particle element.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1, 3, 9, 10, 12, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The claims are unclear since the term roughness and counts of sandpaper are not standards when dealing with elements that do not contain an average particle size. Furthermore the claim deals with a cross section having a roughness equivalent to terms of sandpaper. The examiner is confused with this language and due to the failure to claims certain essential elements (particles with the appropriate particle size in the flange) it is unclear how to determine roughness. The specification fails to shed light on this issue because on page 24 line 23-28, the applicant discloses the use of ridges to increase roughness.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the particles in the flange.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 9, 10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al. (USPN 5,407,431), in view of Ericson et al. (US Pub 20010014996 A1) and Skakoon et al. (USPN 4,804,368).

Botich et al. discloses a pre-filled syringe (Col. 11, lines 14-24) with a syringe barrel comprising a flange that has a front and rear surface, wherein the front surface is roughened (Col. 11, lines 14-24, see figure 1) “to provide a greater coefficient of friction”. The grooves (83) have a regular patterned of roughness since each groove is roughened and the roughness has a convex and concave pitch over the front surface of the flange because of the valleys and ridges that are formed by the grooves (83). Botich et al. fails to disclose “wherein the cross section of the roughened surface has a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper” and “wherein at least one of the front and rear surface is randomly roughened”.

Ericson et al. discloses a wedge clamp type termination for elevator tension members, but more importantly Ericson et al. teaches using sandblasting to raise the

coefficient of friction of a surface (paragraph [0036]). Ericson et al. further teaches other methods of increasing the surface friction, which include etching, machining, knurling and other suitable equivalents.

Skakoon et al. discloses an infusion apparatus with a cylinder holder that includes a flange insertion groove that allows all different types of syringes to fit into the cylinder holder (Column 5, line 15-35).

Therefore, at the time of the invention it would have been obvious to use sandblasting as another means of roughening the front surface of the flange to create a greater coefficient of friction between the fingers and thumb because it is well known that there are many methods that can be used to increase surface friction as taught by Ericson et al. By using this method of increasing the coefficient of friction, the cross section of the roughened surface having a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper would be an obvious modification since the range lacks any criticality or special feature and thus such a range would have been obvious to one skilled in the art wishing for a particular roughness and friction.

The examiner would also like to note that by using sandblasting, it would cause random roughening because sand is being blasted into the object, thus causing the sand to be randomly placed into the object due to the force being exerted on the sand, thus creating a random pattern after each injection. This pattern can be controlled and follow a regular pattern if this method is used to form sections of roughened areas, thus creating a regular pattern from the roughened areas. Ericson et al. also teaches the

formation of small ridges and valleys, which further supports the fact that the roughened section will have a convex and concave pitch (paragraph [0036]).

It would also be obvious to combine the teachings of Botich et al. and Ericson et al. with Skakoon et al., because Skakoon et al. discloses the benefit of using an automated infusion apparatus because the apparatus allows for a more precise and accurate way to infuse drugs and treatment into a patient (Column 2, line 48-55).

### ***Response to Amendment***

3. The affidavit under 37 CFR 1.132 filed 5-15-2008 is insufficient to overcome the rejection of claims based upon the 103 Rejection as set forth in the last Office action because: applicant teaches in this specification the same method and structure as the prior art. The examiner understand the equation presented in the affidavit but until the indefinite issue is resolved in the claim, it seems that the prior art would teach the claimed invention since applicant discloses the same type of structure on page 24, lines 23-28.

### ***Response to Arguments***

4. Applicant's arguments filed 05-15-08 have been fully considered but are not persuasive.

5. The examiner maintains the rejection based on the specification of applicant since on page 24 line 23-28, applicant mentions that concave-convex ridges would roughen the surface of the flange, this provides the appropriate support to state that the mention ranged in the claim is met due to the lack of teachings of how to find the roughness of non particle elements in terms of counts of sandpaper.

6. With regards to the NPL – submitted in the IDS, the NPL teaches figuring out roughness from sandpaper that already has a particles and a grit size. The NPL never discloses how to determine a sand paper roughness from non-particle elements.

7. The examiner is not convinced with the affidavits because of applicant's specification, which teaches that concave-convex ridges would roughen the surface of the flange and cause an increase in strength of the flange (since on page 24 line 23-28).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto

/Matthew F DeSanto/  
Primary Examiner, Art Unit 3763